**IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION**

| | | |
|---|---|---|
| **RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,** | ) | **Case #: 3:05-00444** |
| | ) | **Judge Trauger** |
| **Plaintiff,** | ) | |
| **-against-** | ) | |
| **PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC and JOHN DOE(S) 1-10,** | ) | |
| **Defendants.** | ) | |

**PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE ALL EVIDENCE OF OR REFERENCES TO CONDUCT UNRELATED TO NEURONTIN[1]**

## INTRODUCTION

Defendants Pfizer Inc. and Warner-Lambert Company LLC have moved to exclude at trial any and all evidence of or reference to (i) the August 2009 Settlement with the United States Department of Justice and other government agencies ("Off Label Marketing Settlement"), and (ii) a plea agreement between the Government and Pharmacia & Upjohn Company, Inc. relating to the drug Bextra ("Pharmacia guilty plea").

Upon information and belief, including statements made in Defendants' Answer to the Amended Complaint, Defendants will assert that they do not engage in off-label marketing. The Off Label Marketing Settlement and related Pharmacia Guilty Plea are relevant evidence of (i) Defendants' pattern and practice of marketing pharmaceuticals for off-label purposes, and (ii)

[1] Plaintiff does not concede that the information Defendants attempt to exclude through their motion is in fact "unrelated to Neurontin."

Defendants' previous and contemporaneous use of the marketing tactics Plaintiff alleges Defendants used to further their wrongful promotion of Neurontin for off-label uses. The information is relevant, and is not barred by any Rules of Evidence or caselaw. Plaintiff is within her rights to use this evidence to establish her case, contradict testimony of Defendants' witnesses, and refute contentions put forward in certain Defendants' exhibits.

## FACTS

### A. Off Label Marketing Settlement

In August of 2009, Pfizer entered into a settlement agreement with the United States that resolved claims related to thirteen different drugs.[2] Pfizer agreed to pay $1 billion, plus interest, and the United States agreed to release certain claims against Pfizer.[3]

The settlement resolved, in part, the United States' claims that (i) Pfizer marketed four drugs for unapproved indications and doses and (ii) Pfizer paid health care professionals to induce them to promote and prescribe the same four drugs.[4] The drugs in question were Bextra, Geodon, Zyvox, and Lyrica.[5] Pfizer acknowledged in the settlement agreement that at all relevant times, Pfizer developed, manufactured, distributed, marketed and sold Bextra, Geodon, Zyvox, and Lyrica[6] in the United States.[7]

---

[2] *See* Settlement Agreement, attached to the Declaration of Kenneth B. Fromson, Esq., submitted herewith, as Exhibit A, at p. 1.
[3] Fromson Decl., Ex. A at p. 6, ¶ 1; p. 9, ¶ 2.
[4] Fromson Decl., Ex. A at pp. 3-4, ¶¶ (1)-(4). The settlement also resolved certain alleged kickbacks related to the drugs Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec.
[5] *Id*.
[6] Richard Smith's prescribing physician testified at his deposition that he prescribed Neurontin to Richard Smith for "pain relief," an off-label use, (D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1679-13, 28:14-19), but that "If Mr. Smith came into my office today, I would not prescribe him Neurontin as – he would have gotten Lyrica." *Id.* at 92:21-93:2. The Off Label Marketing Settlement alleged, in part, that "During the period September 1, 2005, through October 31, 2008, Pfizer: (a) illegally promoted the sale and use of Lyrica for a variety of off-label conditions (including chronic pain, neuropathic pain, perioperative pain, and migraine), in violation of the FDCA . . ." Docket No. 108-1, Preamble paragraph F(4), at 5. Under the Off-Label Marketing Settlement, Pfizer agreed to settle this part of their covered conduct for the sum of $48,223,886. *Id.* at 15. This demonstrates that Pfizer continued to illegally promote the sale of Lyrica, the successor to Neurontin, for off-label uses even after Pfizer had already pled guilty to illegally promoting the sale of Neurontin for off-label uses earlier in May 2004.

"Pfizer expressly denies the allegations of the United States and the Relators as set forth herein... and denies it engaged in any wrongful conduct in connection with the Covered Conduct except as to: 1) such admissions as Pharmacia makes in connection with any guilty plea and as provided herein; and 2) the facts set forth in Attachment A as to Zyvox."[8] Attachment A states, in part:

- "This statement reflects facts as to which Pfizer and the United States agree are true and accurate."[9]
- "Pfizer did not provide adequate guidance to its sales force regarding what statements were permissible and what promotional statements were not permitted." ¶ 8.
- "As a result, Pfizer's sales personnel thereafter continued to make claims to physicians that Zyvox was superior to [another drug] for certain patients . . . which included that claim that Zyvox would have a higher cure rate, and would save more lives, despite the fact that these claims were inconsistent with . . . Zyvox's approved label, and which were inconsistent with the manner in which Pfizer, after the receipt of [a] Warning Letter, agreed to present the clinical data cited by the FDA." ¶ 9.

**B. Pharmacia Guilty Plea**

Pfizer acquired Pharmacia (including Pharmacia & Upjohn Company, Inc., Pharmacia & Upjohn LLC, Pharmacia & Upjohn Company, and Pharmacia Corporation) in April 2003.[10] Prior to April 2003, Pfizer jointly promoted the drug Bextra with Pfizer.[11]

In August of 2009, in conjunction with the Off-Label Settlement by Pfizer, Pharmacia agreed to plead guilty to a one-count Information charging Pharmacia with Introduction into Interstate Commerce of a Misbranded Drug (21 U.S.C. §§ 331(a) , 333(a)(2) and 352(0(1)). The information charged, "[Pharmacia] with intent to defraud and mislead, did introduce ... into

---

[7] Fromson Decl., Ex. A, at p. 1, ¶ A.
[8] Fromson Decl., Ex. A, at pp. 5-6, ¶ H (emphasis added).
[9] Attachment A to the Settlement Agreement, Fromson Decl., Ex. B.
[10] *See* Letter regarding Pharmacia Plea Agreement, Fromson Decl., Ex. C; Pharmacia Criminal Information, Fromson Decl., Ex. D, at 1.
[11] Fromson Decl., Ex. D at ¶ 2.

interstate commerce . . . quantities of Bextra . . . which was intended for use for the treatment of acute pain, surgical pain, other unapproved uses, and at unapproved dosages.". Pharmacia stated, "Pharmacia expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the attached Information and is in fact guilty of the offense, and agrees that it will not make any statement inconsistent with this explicit admission."[12]

The information is replete with details about the promotion of Bextra for off-label purposes, including:

- Bextra was promoted off label for general acute pain (¶¶ 23-32);
- Bextra was promoted off label for surgical pain (¶¶ 39-51); and
- Bextra was promoted off label for prevention of deep vein thrombosis (¶¶ 52-54).

The information is also replete with details about Pfizer's use of particular marketing tactics that Plaintiff alleges Pfizer used to wrongfully promote Neurontin:

- Pharmacia promoted Bextra for unapproved uses through remuneration to physicians and purported physician consulting arrangements (¶¶ 33-38);
- Pharmacia sales representatives promoted Bextra by telling physicians Bextra was safer and more effective than Vioxx when Pharmacia knew there were no studies confirming superior efficacy and that Bextra was not approved to treat acute pain. (¶¶ 55-58);
- Pharmacia used purportedly independent Continuing Medical Education to Promote Bextra for unapproved uses and dosages (¶¶ 69-72);
- Bextra was promoted off-label by distributing samples for unapproved uses/doses (¶¶ 64- 68); and
- Bextra was promoted for unapproved uses and dosages by supporting and drafting publications (¶¶ 73-75).

These marketing activities allegedly occurred both before and after Pfizer acquired Pharmacia in 2003.

[12] Fromson Decl., Ex. C, at p. 1.

## ARGUMENT

## POINT I

## THE OFF-LABEL SETTLEMENT AND PLEA AGREEMENT ARE RELEVANT TO PLAINTIFF'S CLAIMS (RULE 401, RULE 402)

Relevant evidence is any "evidence having any tendency to make the existence of any fact that is of consequence to the determination o the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. "[A]11 relevant evidence is admissible, except as otherwise provided." Fed. R. Evid. 402.

The Off Label Marketing Settlement and Pharmacia Guilty Plea are relevant for two distinct yet related reasons. First, they provide evidence that Pfizer has a history of promoting drugs for off-label and unproven purposes. Second, they provide evidence that Pfizer previously used the same improper marketing techniques Plaintiff claims Pfizer used to carry out its wrongful promotion of Neurontin for off-label uses.

## POINT II

## PFIZER HAS A PATTERN AND PRACTICE OF MARKETING DRUGS FOR OFF-LABEL PURPOSES

Plaintiff alleges that Pfizer marketed Neurontin for off-label and unproven purposes. Pfizer denies that it marketed Neurontin for off-label purposes. *See, e.g.*, Defendants' Answer to Amended Complaint, dated July 15, 2009, D. Mass. No. 1:04-cv-10981-PBS, Docket No. 2008. Unless Pfizer is willing to stipulate that they marketed Neurontin for off-label purposes, Plaintiff is entitled to offer evidence in support of this allegation.

The Off Label Settlement Agreement and Guilty Plea provide evidence that Pfizer has repeatedly engaged in marketing prescription drugs for off-label purposes. *See* Fact Section, pp. 2-4, *supra*. These documents at minimum suggest, if not establish, that Pfizer has unlawfully

marketed at least four drugs — aside from Neurontin — for off-label purposes. These documents establish Defendants' knowledge of off-label use and Defendants' common use of the strategy of off-label promotion of their products during the relevant time period. This pattern of behavior has the requisite tendency to make it more likely that Pfizer marketed Neurontin for off-label purposes. *See* Fed. R. Evid. 402.

The Off Label Settlement and Guilty Plea also provide evidence that Pfizer used the same tactics to market other drugs as Plaintiff alleges Pfizer used to further its wrongful promotion of Neurontin for off-label uses. Specifically, Pfizer/Pharmacia promoted Bextra for unapproved uses and doses by compensating physicians through consulting arrangements, utilizing seemingly independent Continuing Medical Education programs, providing remuneration to physicians through consulting arrangements; distributing samples for unapproved uses/doses; and engaging in a publication program. *See* Fact Section, pp. 2-4 *supra*. These are the same techniques that Plaintiff claims Pfizer used to effectuate its wrongful promotion of Neurontin for off-label uses. *See generally*, Amended Complaint, dated April 7, 2008, D. Mass. No. 1:04-cv-10981-PBS, Docket No. 1209.

## POINT III

## THE PROBATIVE VALUE OUTWEIGHS ANY PREJUDICE TO DEFENDANTS (RULE 403)

"[O]nly unfair prejudice factors into the Rule 403 analysis." *United States v. Lloyd*, No. 04-4014, 2006 U.S. App. LEXIS 22642, at *17 (6th Cir. Aug. 18, 2006). Evidence "is unfairly prejudicial if it arouses a sense of horror or otherwise produces an emotional response that would cause the jury to base its decision on something other than the evidence." *United States v. Adames*, 56 F.3d 737, 742 (7th Cir. 1995). "To the claim that the jury will be unduly prejudiced by the introduction of a plea of guilt despite the opportunity to explain it away, we content

ourselves with the statement that this underestimates the intelligence of jurors." *Ando v. Woodberry*, 8 N.Y.2d 165, 171, 168 N.E.2d 520, 524 (N.Y. 1960).

> Where a party assumes a certain legal position in a proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position, especially if it be to the prejudice of the party who has acquiesced in the position formerly taken by him.

*Davis v. Wakelee*, 156 U.S. 680, 689 (1895). Courts have admitted even non-parties' guilty pleas against civil defendants. *See, e.g.*, *RSBI Aerospace, Inc. v. Affiliated FM Ins. Co.*, 49 F.3d 399, 401, 403 (8th Cir. 1995) (non-party employee's guilty plea and accompanying sworn statement were admissible against defendant in subsequent civil case); *Newby v. Enron Corp.*, 491 F. Supp. 2d 690, 703 (S.D. Tex. 2007) (non-party's guilty plea was admissible against defendants in subsequent civil case).

Any prejudice that may result from the introduction of evidence related to the Off Label Settlement and Pharmacia Guilty Plea is related to Plaintiff's allegations that Pfizer engaged in off-label, illegal marketing of pharmaceuticals, the very allegations that form the heart of Plaintiff's case. Any prejudice is therefore not undue. Plaintiff is not attempting to shoehorn an unrelated criminal plea and investigation into this matter in order to make Pfizer look like "bad actor" (Pfizer's instance to the contrary notwithstanding, *see* Defs. Mem., Docket No. 107, at 2, 13-15). Instead, Plaintiff seeks to introduce evidence of a settlement and plea that involve strikingly similar actions taken by Pfizer with respect to other prescription drugs during the same time period.[13]

[13] The guilty please was entered by Pharmacia in 2009. Pfizer marketed Bextra with Pharmacia as a joint venture prior to acquiring Pharmacia outright in 2003. To the extent that Pfizer maintains the guilty plea of a non-party is not admissible, they are mistaken. *See e.g.*, *RSBI Aerospace, Inc. v. Affiliated FM Ins. Co.*, 49 F.3d 399, 401, 403 (86 Cir. 1995) (admitting non party's guilty plea); *Newby v. Enron Corp.*, 491 F. Supp. 2d 690, 703 (S.D. Tex. 2007) (admitting non-party's guilty plea).

Pfizer should not be allowed to assume a contrary position, that it did not engage in these off-label practices. Plaintiff should be allowed to introduce evidence of the Pharmacia Guilty Plea to show that Pfizer has continued to engage in similar, if not identical, activities with regard to Neurontin. Pfizer was well-aware of what it was buying when it purchased Pharmacia and it continued to profit from the misconduct involved in the Plea that mirrors the conduct in this case.

Pfizer's claim that "[t]here is simply no way to adequately address the issues related to the August 2009 Settlement and Pharmacia Plea in a way that would be both fair and would not overwhelm the jury" is not genuine. Docket No. 107, at 6. Pfizer could easily (i) stipulate to the fact that they engaged in off-label marketing of Neurontin (in which case this evidence may well become unnecessary), (ii) tell the jury that they paid $1 billion so that they would no longer have to deal with the hassle of ongoing litigation with the Federal Government, (iii) tell the jury that they did not market any drugs off label, or (iv) tell the jury that Plaintiff has misconstrued the settlement. Pfizer may also ask the Court to redact these documents, or give a limiting instruction to the jury. *Miller v. Holtzmann*, 563 F. Supp. 2d 54, 82 (D.D.C. 2008). Pfizer is free to give the jury any explanation it desires; but the lack of a compelling explanation for why Pfizer and Pharmacia entered into settlement agreements and guilty pleas is not a sufficient reason to prevent Plaintiff from introducing the evidence.

Defendants cannot claim undue prejudice when the prejudice results from Defendants' action that are directly related to the claims in the case simply because they think it will be tricky to explain away a previous related transgression to a jury.

## POINT IV

## THE OFF-LABEL SETTLEMENT AND PLEA AGREEMENT ARE NOT INADMISSIBLE UNDER RULE 408

Rule 408 only prohibits the introduction of statements from settlement agreements to prove liability for the underlying claim, not the use of such documents to show evidence of previous allegations of similar behavior. To the extent that the Off Label Settlement and Plea Agreement contain facts relating to Pfizer's off-label marketing strategy, Plaintiff seeks to introduce them as admissible "evidence of unqualified factual assertions." Fed. R. Evid. 408, Notes of Committee on the Judiciary, House Report No. 93-650; Notes of Committee on the Judiciary, Senate Report No. 93-1277; *see also United States v. Warren*, No. 7:04 CR 00021, 2005 U.S. Dist. LEXIS 9269 at *9 (W.D. Va. May 17, 2005) (district court ruled the document admitted for purpose other than proof of liability, meeting exception to general rule); *United States v. Gilbert*, 668 F.2d 94, 97 (2d Cir. 1981) (SEC consent decree admissible to show that defendant was aware of SEC reporting requirements); *Johnson v. Hugo's Skateway*, 974 F.2d 1408, 1413 (4th Cir. 1992) (Rule 408 applicable to a consent order, which could be admitted for limited purpose of showing motive and intent).

## POINT V

## THE OFF-LABEL SETTLEMENT AND PLEA AGREEMENT ARE ADMISSIONS, NOT HEARSAY

Where evidence is not being presented to prove the truth of the matter, it is by definition not hearsay. *See United States v. Riley*, 684 F.2d 542 (8th Cir. 1982) (guilty plea constitutes admission, and as such is admissible in defendant's federal prosecution); *Carlsen v. Javurek*, 526 F.2d 202 (8th Cir. 1975) (in suit for wrongful death of plaintiff's wife allegedly resulting from negligent selection and administration of drug, evidence that plaintiff had pled guilty to assault

charge against his wife may be admissible as admission of party to lawsuit under Rule 801(d)(2)); *Bartholomew v. Unum Life Ins. Co. of Am.*, 588 F. Supp. 2d 1262 (W.D. Wash. 2008) (settlement agreement was not admissible as evidence of liability, but as admission of party opponent under Fed. R. Evid. 801(d)(2); admissible and relevant to extent that it demonstrated that concerns had historically been raised regarding administrator's claims-handling practice).

**POINT VI**

**INTRODUCTION OF THE PLEA AGREEMENT**
**DOES NOT VIOLATE DEFENDANTS' DUE PROCESS RIGHTS**

Defendants assert that introduction of the Guilty Plea will result in a violation of their due process rights. Docket No. 107, at 9-13. Defendants are mistaken.

First, particularly in light of the restrictions on the length of the trial, Plaintiff will not spend time trying to prove that Pfizer is guilty of acts that have already been resolved in previous settlements. Defendants will not have to defend against them, and thus there is no risk of prolonged mini-trials.

Second, Plaintiff has never indicated that she intends to introduce evidence of past settlements and guilty pleas as a basis for seeking punitive or multiple damages. Plaintiff does not intend to use the Off Label Settlement and Guilty Plea for such a purpose. If Defendants' concern is that a jury may so loathe Pfizer upon hearing about its $1 billion dollar settlement that they could not help but impose punitive damages, Defendants are free to suggest a limiting jury instruction. Of course, if juries are truly so easily swayed, then there is not much hope for our judicial system.

## POINT VII

## THE OFF-LABEL SETTLEMENT AND PLEA AGREEMENT MAY BE PROPERLY ADMITTED AS IMPEACHMENT EVIDENCE

Even if the Court rules that Plaintiff may not offer the Off Label Settlement and Plea Agreement for the purposes outlined above, at a minimum Plaintiff seeks to utilize these documents for the more limited purpose of impeachment.

Rule 609 allows for the use of the Plea for the purposes of attacking the character for truthfulness of a witness (other than the accused) where the prior act involved dishonesty, such as in the false representations involved in the Pharmacia Plea. Fed. R. Evid. 609(a). Meanwhile, Rule 408 only prohibits certain uses of this evidence, and describes "permissible purposes include proving a witness's bias or prejudice" and "negating a contention of undue delay." Fed. R. Evid. 408. Finally, Rule 803 allows for the use of a final judgment, such as a plea of guilt, to prove any fact essential to sustain that judgment. Fed. R. Evid. 803(22).

In this instance, the underlying facts involved in the Off Label Settlement and Plea Agreement are essential to Plaintiff's case. Here, it is alleged that Pfizer has engaged in just the same sort of behavior as described in these documents. *See Scholes v. Lehmann*, 56 F.3d 750 (7th Cir. 1995) (Ponzi scheme mastermind's plea agreement admissible under Fed. R. Evid. 803(22) in SEC's civil suit against him and his corporations, charging violations of federal securities laws). Likewise, Pfizer cannot now claim that it has not engaged in off-label marketing, by seeking to show evidence which tends to refute that claim. *See United States v Bennett*, Crim. No. 06-00068 SOM, 2008 U.S. Dist. LEXIS 42995 (D. Haw. May 30, 2008) (defendant testified to good faith belief that tax laws did not require filing tax return or paying taxes; evidence of felony convictions of defendant's tax advisor and associates was not

inadmissible under Fed. R. Evid. 803(22) since government was entitled to impeach using convictions to show defendant held no such good faith belief).

## CONCLUSION

In view of the above, it is respectfully requested that the Court deny in its entirety Defendants' Motion *in Limine* to Exclude all Evidence or References to Conduct Unrelated to Neurontin.

Dated: April 27, 2010

Respectfully submitted,

THE LANIER LAW FIRM, P.L.L.C.

By: **/s/ W. Mark Lanier**
W. Mark Lanier, Esq.
Dara G. Hegar, Esq.
Ken S. Soh, Esq.
Maura Kolb, Esq.
Robert Leone, Esq.
126 East 56th Street, 6th Floor
New York, NY 10022

- and -

FINKELSTEIN & PARTNERS, LLP

By: **/s/ Andrew G. Finkelstein**
Andrew G. Finkelstein, Esq.
Kenneth B. Fromson, Esq.
1279 Route 300, P.O. Box 1111
Newburgh, NY 12551

- and -

BARRETT & ASSOCIATES, P.A.

By: **/s/ Charles F. Barrett**
Charles F. Barrett, Esq.
BPR # 020627
6518 Highway 100, Suite 210
Nashville, TN 37205

*Attorneys for Plaintiff Ruth Smith*

**CERTIFICATE OF SERVICE**

I hereby certify that on this the 27th day of April, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

Aubrey B. Harwell, Jr., Esq.
W. David Bridgers, Esq.
Gerald D. Neenan, Esq.
Robert A. Peal, Esq.
Neal & Harwell, PLC
2000 One Nashville Place
150 Fourth Avenue, North
Nashville, TN 37219

Prince C. Chambliss, Jr., Esq.
Evans & Petree, PC
1000 Ridgeway Loop Road, Suite 200
Memphis, TN 38120

Mark S. Cheffo, Esq.
Catherine B. Stevens, Esq.
Skadden, Arps, Slate, Meagher & Flom LLP
Four Times Square
New York, NY 10036

**/s/ Kenneth B. Fromson**
Kenneth B. Fromson